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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,849	10/24/2005	Ce Zhang	13679.2USWO	9593
23552 7590 05/06/2008 MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903				
EXAMINER				
MARX, IRENE				
ART UNIT		PAPER NUMBER		
1651				
MAIL DATE		DELIVERY MODE		
05/06/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/525,849

**Applicant(s)**

ZHANG ET AL.

**Examiner**

Irene Marx

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 1-8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SG/US)
- Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

The application should be reviewed for errors. Error occurs, for example, in the spelling of "cervical" in claim 10.

To facilitate processing of papers at the U.S. Patent and Trademark Office, it is recommended that the Application Serial Number be inserted on every page of claims and/or of amendments filed.

Applicant's election without traverse electing to prosecute the invention of Group III, claims 9-11 on 2/4/08 is acknowledged.

Claims 9-11 are being considered on the merits. Claims 1-8 are withdrawn from consideration as directed to a non-elected invention.

#### *Claim Rejections - 35 USC § 112*

Claim 10 provides for the use of a cell wall skeleton in preparation of an agent for the treatment of cervical erosion, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

#### *Claim Rejections - 35 USC § 101*

Claim 10 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time

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any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haraguchi *et al.* (Jpn J. Cancer Res. (Gann), vol. 76, pages 400-413, May 1985) taken with Azuma *et al.* (Cancer Immunol. Immunother., vol. 4, pages 95-100 (1978)), Xu *et al.* (U.S. Patent No. 6,992,073), and Sutcliffe (Antonie van Leeuwenhoek 74: 49-58, 1998).

The claims are directed to a method for treatment of cervical erosion by applying "directly to a suffering site of subject" a pharmaceutically effective amount of *Nocardia rubra* cell wall skeleton preparation.

Haraguchi *et al.* teach a method of administering *Nocardia rubra* cell wall skeleton preparations by intradermal injection for the treatment of tumors and for the purpose of stimulating the immune system. See, e.g., Bridging paragraph between pages 402 and 403.

Azuma *et al.* teach a method of administering *Nocardia rubra* cell wall skeleton preparations by intradermal injection for the treatment of tumors and leukemia. See, e.g., page 96, col. 2, paragraph 2.

The references differ from the claimed invention in that the treatment of cervical erosion is not disclosed. However, Xu *et al.* teach a method of treating cervical erosion by applying compositions comprising N-acetyl glucosamine directly to the site of suffering to treat cervical erosion (See, e.g., col. 4, lines 55 et seq.). Moreover, Azuma *et al.* discloses that cell wall preparations of *N. rubra* contain at least glucosamine (See, e.g., Table 1), and Sutcliffe discloses that all *Nocardia* contain N-acetyl glucosamine, which would become available upon preparation of cell wall skeleton compositions. (See, e.g., page 50, col. 2, last 5 lines.).

Accordingly, one of ordinary skill in the art would have had a reasonable expectation of success in treating cervical erosion by applying directly to a suffering site of subject a *Nocardia rubra* cell wall skeleton preparation, since it is taught by Xu *et al.* that N-acetyl glucosamine containing compositions provided by microbial cells are useful for this purpose and this material is comprised at least to some extent by the *Nocardia rubra* cell wall skeleton preparation as taught by Azuma *et al.* and Sutcliffe for the expected benefit of successfully treating the unpleasant and threatening condition of cervical erosion with a natural material which

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additionally has various recognized favorable properties, such as acting to boost the immune system.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Irene Marx/  
Primary Examiner  
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